

Applicants: William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardanov,

Vasan Sambandamurthy and Sheldon Morris

Appl. No.: 10/542,958

Filed: January 30, 2007

page 4 of 5

Remarks

Claims 1, 5, 8, 10, 19, 41 and 87 are pending in the subject application. By this amendment, Claim 1 has been amended to further define applicants' invention. The amendments to Claim 1 are supported by the application as filed and do not introduce new matter. Accordingly, entry of the foregoing claim amendments is respectfully requested.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 1, 5, 8, 10, 19, 41 and 87 were rejected under 35 U.S.C. §112, first paragraph. This rejection is respectfully traversed.

In the Office Action, the Examiner stated that the claimed invention lacks enablement for inoculating any mammal other than a mouse against *M. tuberculosis* using an attenuated *M. tuberculosis* or *M. bovis* which has a deletion of RD1 and is auxotrophic for pantothenate. In this regard, the Examiner focused on statements in Waters, et al. that "vaccination trials with m²6030 failed to protect cynomolgus monkeys from virulent *M. tuberculosis*."

It is noted, however, that Water, et al. stated that "[s]imilar findings with cynomolgus monkey and neonatal calf trials, however, may be indicative of other, non-determined causes of vaccine failure such as inappropriate dose." (see, Waters, et al., page 7839, first paragraph). Claim 1 has been amended to recite that the attenuated *M. tuberculosis* or *M. bovis* mycobacterium is administered in an "amount" "effective to confer protection against *Mycobacterium tuberculosis* in the mammal". In view of this amendment, and the teachings in the specification that the attenuated mycobacterium (having a deletion of RD1 that is auxotrophic for pantothenate) can be administered in an amount effective to confer protection against *M. tuberculosis*, the claimed invention is

Applicants: William R. Jacobs, Jr., Tsungda Hsu, Stoyan Bardanov,
Vasan Sambandamurthy and Sheldon Morris
Appl. No.: 10/542,958
Filed: January 30, 2007
page 5 of 5

believed to be enabled. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSIONS

In view of the amendments and remarks made hereinabove, reconsideration and withdrawal of the rejections set forth in the November 5, 2009 Office Action and passage of the pending claims to allowance are respectfully requested. If there is any minor matter preventing the allowance of the subject application, the Examiner is requested to telephone the undersigned attorney.

No fee, other than the \$245 two month extension of time fee, is deemed necessary in connection with the filing of this Amendment. However, if any fee is required to preserve the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785. Overpayments may also be credited to Deposit Account No. 01-1785.

Respectfully submitted

AMSTER, ROTHSTEIN & EBENSTEIN LLP
Attorneys for Applicants
90 Park Avenue
New York, NY 10016
(212) 386-8000

Dated: New York, New York
March 11, 2010

By: *Craig J. Arnold*
Craig J. Arnold
Registration No. 34,287